

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

FILE UNDER SEAL

UNITED STATES OF AMERICA)

v.)

No. 10-cr-694-RWT

LAUREN STEVENS,)

Defendant.)

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION
FOR DISCLOSURE OF THE GOVERNMENT'S PRESENTATION
TO THE GRAND JURY RELATING TO
THE ADVICE OF COUNSEL DEFENSE AND 18 U.S.C. § 1515(c)

INTRODUCTION

Defendant Lauren Stevens respectfully moves, pursuant to Rule 6(e)(3)(E)(ii) of the Federal Rules of Criminal Procedure, for an Order directing the government to disclose grand jury transcripts to Ms. Stevens and the Court to determine whether there was irregularity in the grand jury proceeding warranting dismissal of the Indictment.¹ In this case, where the government is aware from grand jury proceedings in another jurisdiction of significant exculpatory evidence supporting the advice of counsel defense, a government failure to provide the grand jury that indicted the defendant accurate legal instruction and evidence relating to the defense could constitute a serious defect in the grand jury proceedings warranting dismissal of the Indictment. In the alternative, the Court should direct the government to provide relevant portions of the grand jury transcript for the Court's *in camera* review.

¹ Rule 6(e)(3)(E)(ii) of the Federal Rules of Criminal Procedure authorizes disclosure of grand jury transcripts when a defendant shows that "a ground may exist to dismiss the indictment because of matters occurring before the grand jury."

Because the grand jury's investigation of the facts underlying this case has ended and an Indictment has been returned, disclosure will not threaten the secrecy of ongoing grand jury proceedings. On the other hand, failure to disclose the prosecution's instruction and presentation of evidence on the advice of counsel defense would insulate the Indictment from any review for legal defect. If Defendant's constitutional right to indictment by grand jury may be satisfied by obtaining an indictment from a grand jury that has been misled or misinstructed on the governing law, that constitutional right will cease to be a meaningful protection for defendants.

BACKGROUND

The Indictment charges Lauren Stevens with obstruction of justice and false statements based on her involvement in responding to a United States Food and Drug Administration ("FDA") inquiry to GlaxoSmithKline ("GSK" or the "Company") regarding possible off-label marketing of GSK's antidepressant product Wellbutrin SR ("Wellbutrin"). Ms. Stevens was employed at the time as an Associate General Counsel at GSK.²

On October 9, 2002, GSK received a letter from the FDA's Division of Drug Marketing, Advertising, and Communications ("DDMAC") requesting that GSK voluntarily provide certain information relating to the marketing of Wellbutrin. *See* December 17, 2010 Declaration of Brien T. O'Connor ("Decl.") ¶ 6. DDMAC expressed concern that GSK might be improperly "promoting the off-label use" of Wellbutrin "for weight loss." *Id.*

² The Indictment employs pseudonyms when referring to GSK (which has not been charged) and Wellbutrin, and refers only to "K-Corp." and "W-Drug." Defendant has followed this practice in its public filings. Because this motion is filed under seal, Defendant has referred directly to GSK and Wellbutrin rather than use the pseudonyms.

Ms. Stevens led the team that responded to the letter on behalf of GSK. Decl. ¶ 8. The Company engaged the law firm of King & Spalding LLP to participate in preparing GSK's response. The lead King & Spalding attorney advising GSK on this matter was Mark Brown, a former Associate Chief Counsel at the FDA who has served as one of the agency's chief litigators handling both civil and criminal pharmaceutical cases. *Id.* ¶ 10. The team included two other GSK attorneys, Sherrie Shade, the Wellbutrin product attorney, and Doug Snyder, a former FDA Associate General Counsel. *Id.* ¶ 8.

King & Spalding attorneys were intimately involved in the investigation of the underlying facts, the collection of relevant documents, and the preparation of GSK's response. Decl. ¶ 13. GSK and King & Spalding conducted an extensive review of GSK promotional materials, speaker training slides and other documents relating to Wellbutrin. *Id.* King & Spalding personally interviewed over a dozen GSK employees involved in the marketing of Wellbutrin, as well as the three doctors identified in the October 9 FDA inquiry as potentially involved in off-label promotion. *Id.* King & Spalding concluded, on the basis of this review, that GSK did not have a corporate strategy to promote Wellbutrin to achieve weight loss or to treat obesity. *Id.*

GSK sent six substantive letters of response to the FDA between December 2002 and November 2003. Decl. ¶ 14. The letters addressed the FDA's major areas of inquiry and described, in narrative format, GSK's promotional program for Wellbutrin. *Id.* The letters disclosed several instances of noncompliance with corporate policies regarding the marketing of Wellbutrin that GSK and King & Spalding had discovered during their investigation. *Id.* King & Spalding attorneys drafted, edited and reviewed each of these letters. *Id.* ¶ 14. In each case,

the letters were sent to the FDA only after a consensus was reached among the lawyers regarding the response to be made.

The core conclusion of the GSK and King & Spalding team was that, while certain physician speakers may have violated Company policy through statements about Wellbutrin relating to weight loss, GSK had no centralized corporate strategy to promote Wellbutrin off-label to treat obesity. Decl. ¶ 18. Based on this consensus conclusion, GSK stated in a February 28, 2003 letter to the FDA:

- a. GSK has not developed, devised, established or maintained any program or activity to promote or encourage, either directly or indirectly, the use of Wellbutrin SR as a means to achieve weight loss or treat obesity. . . . GSK's promotional material and activities for Wellbutrin SR are consistent with the approved Prescribing Information and supporting clinical data.
- b. GSK has not developed or maintained promotional plans or activities to directly or indirectly promote Wellbutrin SR for weight loss or the treatment of obesity.

Id. ¶ 17.

The Indictment alleges that Ms. Stevens made these and similar statements knowing they were false. *See* Indict. Counts 3 to 6.

GSK also voluntarily produced documents and other information requested by the FDA. Early in the investigation, GSK told an FDA representative that the Company would make a good-faith effort to obtain from physicians under contract with GSK, and to provide to DDMAC, materials presented by physician speakers at GSK-sponsored promotional programs. Decl. ¶ 20. Accordingly, the team sent out requests to over 500 physicians, 40 of whom returned speaker presentations. *Id.* ¶¶ 21-22. GSK forwarded all of the materials it received to King & Spalding, which reviewed each of the presentations to determine whether any of the slides were off-label. *Id.* ¶ 22. The team concluded that while some of the slides did contain potentially off-label

content, it was impossible without extensive interviews of doctors to determine how or if the presentations had been used and what the physicians actually said at their presentations. *Id.*

The GSK and King & Spalding team discussed at length whether to produce the presentations to the FDA absent the context necessary to assess the presentations. Decl. ¶ 23. The team was concerned that simply producing the presentations with no explanation could create a misleading impression. The GSK and King & Spalding legal team reached a consensus not to produce the presentations immediately but instead to seek a meeting with the FDA at which GSK would discuss the presentations. *Id.* Ms. Stevens called the FDA several times in May/June 2003 to schedule such a meeting. *Id.* ¶ 24. However, the FDA did not respond to Ms. Stevens' calls, and the anticipated meeting never occurred. *Id.* At no time did King & Spalding advise GSK that its failure to produce the presentations was unlawful. *Id.* ¶ 23.

In 2004, the Department of Justice began a broad investigation of GSK addressing multiple GSK products and issues. In connection with that investigation, GSK produced the presentations that it had collected in response to the earlier FDA inquiry. *Id.* ¶ 24.

On May 5, 2009, the government sent a "target" letter to Ms. Stevens stating that if an indictment were issued, the venue would be Greenbelt, Maryland. *Id.* ¶ 26. Nonetheless, throughout 2009 and 2010, the government appears to have obtained evidence against Ms. Stevens from witnesses who testified in front of a grand jury in the United States District Court for the District of Massachusetts. The testimony of some of these witnesses, including attorneys from King & Spalding and GSK's own legal department, almost certainly included the fact that lawyers from King & Spalding and other GSK lawyers participated in drafting all of the letters at issue and the decision-making regarding whether to produce the physician

presentations. Because good-faith reliance on the advice of counsel is critical to the issue of intent, such testimony has the potential to be highly exculpatory.

On November 8, 2010, the government obtained the Indictment against Ms. Stevens from the grand jury in the United States District Court for the District of Maryland charging Ms. Stevens with knowingly making false statements in the GSK letters to the FDA and with obstructing justice by not producing the presentations that GSK had collected from physician speakers. The government did not charge any other member of the GSK or King & Spalding legal teams or GSK itself with any crime relating to the FDA submissions or the nonproduction of the physician presentations.

To the extent that the testimony of the King & Spalding and other GSK lawyers who testified pursuant to a subpoena from the Massachusetts grand jury was exculpatory, Ms. Stevens does not know if the government ever presented such testimony to the Maryland grand jury that indicted her. To the knowledge of defense counsel, none of the King & Spalding or GSK lawyers were called as witnesses before the Maryland grand jury. Defense counsel has no ability to determine if the grand jury in Maryland was provided complete transcripts of the Massachusetts testimony, or no disclosure of such testimony at all.

In sum, Ms. Stevens has grounds to believe that the grand jury transcripts may provide a basis for a motion to dismiss the Indictment for irregularities in the grand jury proceedings based upon a failure to instruct the Maryland grand jury about the advice of counsel defense and the substantial evidence supporting such a defense.

ARGUMENT

I. The Court Should Order Disclosure to the Defense of Those Portions of the Grand Jury Transcripts Reflecting Any Government Statements, Instruction or Presentation of Evidence Concerning the Advice of Counsel Defense and 18 U.S.C. § 1515(c)

A. The Rule 6(e)(3)(E)(ii) Standard

Rule 6(e)(3)(E)(ii) authorizes the Court to order disclosure of a grand jury matter “at the request of a defendant who shows that a ground may exist to dismiss the indictment because of a matter that occurred before the grand jury.” To obtain disclosure, a defendant must demonstrate “that particularized and factually based grounds exist to support the proposition that irregularities in the grand jury proceedings may create a basis for dismissal of the indictment.” *United States v. Harris*, No 5:07-CR-22, 2007 WL 1724298 at *5 (N.D.W.Va. June 14, 2007) (quoting *United States v. Abcasis*, 785 F.Supp. 1113, 1119 (E.D.N.Y. 1992)). Once a particularized and factually based need has been shown, the Court may order disclosure, subject to appropriate protections in the Court’s discretion, of those grand jury materials needed in order to pursue a motion to dismiss. *See United States v. Johnson*, 337 F.2d 180, 197 (4th Cir. 1964) (“[W]here there is a particularized need for grand jury minutes, it is within the sound discretion of the district court to require their production.”); *United States v. Naegele*, 474 F. Supp. 2d 9, 11-12 (D.D.C. 2007) (“only a complete review of the entire Grand Jury proceeding can illuminate the extent of the government’s reliance on the [defective evidence] to obtain all remaining counts of the Indictment.”). Alternatively, the Court may review the grand jury transcripts *in camera* to determine the extent to which the transcript should be disclosed. *See United States v. Twersky*, No. S2 92 Cr. 1082 (SWK), 1994 WL 319367, at *5 (S.D.N.Y. June 29, 1994) (ordering disclosure for *in camera* review); *United States v. Jefferson*, 546 F.3d 300,

306 (4th Cir. 2008) (noting the district court reviewed portions of the grand jury record *in camera* that the prosecution had not provided to the defendant).

The evidence herein more than demonstrates a “factually based showing of particularized need” for the grand jury transcripts. *Naegele*, 474 F. Supp. at 11. If the government failed to instruct the grand jury on the potential applicability of the advice of counsel defense, and or to present exculpatory evidence regarding that defense, in addition to other procedural irregularities discussed, there would exist ample grounds to dismiss the Indictment. Rule 6(e)(3)(E)(ii). Accordingly, the Court should order the government to disclose all parts of the grand jury transcripts reflecting the government’s instruction, argument or statements regarding the applicability of the advice of counsel defense to this case.

B. A Failure to Instruct the Grand Jury on the Advice of Counsel Defense and 18 U.S.C. § 1515(c) and to Present Significant Exculpatory Evidence Would Raise Serious Concerns

The grand jury is intended to be a check against unfounded prosecution—a shield between the citizen and the prosecutorial power of the government. “Historically, this body has been regarded as a primary security to the innocent against hasty, malicious and oppressive persecution; it serves the invaluable function in our society of standing between the accuser and the accused . . .” *Wood v. Georgia*, 370 U.S. 375, 390 (1962). The grand jury “provide[s] a shield against arbitrary or oppressive action, by insuring that serious criminal accusations will be brought only upon the considered judgment of a representative body of citizens acting under oath and under judicial instruction and guidance.” *United States v. Mandujano*, 425 U.S. 564, 571 (1976) (plurality).

The grand jury must rely entirely on the prosecutor for instruction on the law. *See United States v. Sells Engineering*, 463 U.S. 418, 430 (1983) (“The prosecutor also advises the lay jury

on the applicable law.”).³ “As a legal advisor to the grand jury, the prosecutor must give the grand jury sufficient information concerning the relevant law ‘to enable it intelligently to decide whether a crime has been committed.’” *Twersky*, 1994 WL 319367, at *4 (citation omitted). Since the prosecutor’s guidance is the only guidance the grand jury receives, it is critical that the prosecutor’s statements of law be fair and accurate.

The law is clear that where a defendant relies in good faith on advice of informed counsel, she lacks the intent necessary for a criminal conviction. *United States v. Miller*, 658 F.2d 235, 237 (4th Cir. 1981) (stating that the reliance defense “is designed to refute the government’s proof that the defendant intended to commit the offense”). In this case, the advice of counsel defense is a critical component of the law necessary to determining whether the defendant had the requisite criminal intent. *Id.* (defendant charged with making false statements is entitled to an instruction explaining the defense of reliance on expert advice when proper factual foundation is laid). If a defendant acts in good faith relying on counsel’s advice, “it cannot be said that the defendant ‘knowingly’ submitted false information . . . even if that advice turns out in fact to be false.” *United States v. Newport News Shipbuilding, Inc.*, 276 F. Supp. 2d 539, 565 (E.D. Va. 2003). Reliance on advice of counsel negates the intent necessary for a defendant to be guilty of violating statutory prohibitions against false statements and obstruction of justice, *see Miller*, 658 F.2d at 237; *United States v. Butler*, 211 F.3d 826, 833 (4th Cir. 2000).⁴

³ *See also United States v. Singer*, 660 F.2d 1295, 1303 (8th Cir. 1981) (prosecuting attorney “serves as ‘the guiding arm of the grand jury’”) (citation omitted).

⁴ To obtain a conviction under 18 U.S.C. § 1001 (2006), the government must prove that a defendant knowingly and willfully made a false statement. Similarly, 18 U.S.C. § 1512(c) (2006 & Supp. II 2008) requires that a person have altered, destroyed or concealed a document “with the intent to impair the object’s integrity or availability for use in an official proceeding.”

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Similarly, the obstruction statute, 18 U.S.C. § 1515(c), specifically includes a safe harbor provision that provides a complete defense for a defendant-lawyer who provides *bona fide* legal representation. Under that statute, “one who is performing bona fide legal representation does not have an improper purpose. His purpose -- to zealously represent his client -- is fully protected by the law.” *United States v. Kloess*, 251 F.3d 941, 948 (11th Cir. 2001).⁵ Therefore, § 1515(c) constitutes an affirmative defense which negates an element of the obstruction offense and, once raised by the defense, shifts the burden to the government to prove beyond a reasonable doubt that the defendant’s conduct “did not constitute lawful, *bona fide* legal representation.” *Id.* at 948-49. Such an instruction could have a profound effect on the grand jury’s decision of whether to indict Ms. Stevens.

Here, the advice of counsel defense (and related defense under § 1515(c)) goes to the central question the grand jury was asked to decide—whether there is a basis for prosecution of Ms. Stevens based on intentionally fraudulent misstatements and obstruction of justice. If the government failed to instruct the grand jury on or present evidence of the advice of counsel defense, such omission would constitute a serious defect in the grand jury proceedings that would support dismissal of the Indictment because it could well have resulted in an indictment

To establish an obstruction of justice charge under 18 U.S.C. § 1519 (2006), the government must prove that a defendant knowingly concealed or covered up documents or tangible objects, or made false entries in documents, with the intent to obstruct.

⁵ *See also* 132 Cong. Rec. 32805 (1986) (analysis of legislation that became § 1515(c)) (“Vigorously and zealously representating a client . . . is not a basis for charging an offense under the obstruction of justice chapter. Section 50(2) [now § 1515(c)] therefore amends 18 U.S.C. 1515 to provide specifically that the lawful, bona fide provisions of legal representation services does not constitute an offense under any of the obstruction of justice offenses in 18 U.S.C. ch. 73”), *available at* 132 Cong. Rec. H 11291 (daily ed. Oct. 17, 1986) (statement of Rep. George Gekas).

for acts which do not violate the law. *See, e.g., United States v. McDonald*, 61 F.3d 248, 253 (4th Cir. 1995); *United States v. Lawson*, 502 F. Supp. 158, 163 (D. Md. 1980); *Twersky*, 1994 WL 319367, at *4-5.

Testimony of the King & Spalding attorneys regarding the advice of counsel defense is likely to have been highly exculpatory, and would have been critical to the decision whether to indict Ms. Stevens. If in fact such evidence of such an affirmative defense was obtained in testimony in Massachusetts but not presented to the grand jury in Maryland, Ms. Stevens was seriously prejudiced. *See United States v. Walters*, 333 F. Supp. 2d 1022, 1032 (D. Kan. 2004) (prosecutors “must present evidence that clearly negates guilt”) (quoting *United States v. Page*, 808 F.2d 723, 727 (10th Cir. 1987)); United States Attorneys’ Manual, § 9-11.233 (June 2008) (stating that when a prosecutor conducting a grand jury investigation is aware of substantial exculpatory evidence, “the prosecutor must present or otherwise disclose such evidence to the grand jury before seeking an indictment against such a person”).⁶ As the Fourth Circuit stated in *McDonald*, “the government’s creation or acceptance of an erroneous impression” that relates to exculpatory evidence could support a claim for prosecutorial misconduct and dismissal of the indictment if the misconduct prejudiced the defendant. 61 F.3d at 253.^{7 8} *See also Lawson*, 502

⁶ Available at http://www.justice.gov/usao/eousa/foia_reading_room/usam/title9/11mcrm.htm.

⁷ Significantly, *McDonald* was decided *after* the Supreme Court’s decision in *United States v. Williams*, 504 U.S. 36 (1992), in which the Court restricted the review of grand jury proceedings absent certain circumstances.

⁸ In *McDonald*, the defendant alleged that prejudicial prosecutorial misconduct occurred because the government had allowed a Drug Enforcement Agency agent to inform the grand jury that two other witnesses had taken polygraph tests, but had misled the grand jury by implying that the witnesses had passed the tests when in fact one’s results were inconclusive and the other’s indicated deception. 61 F.3d at 252. The Fourth Circuit agreed that the agent’s reference to polygraph tests was improper, but concluded that the complete results of the tests would not have exculpated the defendant because there was other substantial evidence against the defendant

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F. Supp. at 163 (dismissing indictment where prosecutor found to have deliberately placed false and misleading evidence before the grand jury to create a false impression).

Where irregularities infect the grand jury process, courts will dismiss the indictment “‘if it is established that the violation substantially influenced the grand jury’s decision to indict,’ or if there is ‘grave doubt’ that the decision to indict was free from the substantial influence of such violations.” *Bank of Nova Scotia v. United States*, 487 U.S. 250, 256 (1988) (quoting *United States v. Mechanik*, 475 U.S. 66, 78 (1986)).⁹ Ms. Stevens respectfully requests that the Court order disclosure of the grand jury transcripts to determine whether the government provided the grand jury in Maryland with summaries and transcripts relating to Ms. Stevens’ advice of counsel defense, or otherwise informed the grand jurors of the facts relevant to this basic defense. Disclosure of these specific materials is necessary “to avoid a possible injustice” and is “greater than the need for continued secrecy.” *Id.* (quoting *Douglas Oil Co. v. Petrol Stops Northwest*, 441 U.S. 211, 222 (1979)); *see also United States v. McGowan*, 423 F.2d 413, 418 (4th Cir. 1970) (“[A]fter the grand jury’s functions are ended, disclosure is wholly proper where the ends of justice require it.”) (quoting *United States v. Socony-Vacuum Oil Co.*, 310 U.S. 150, 234 (1940)).

both before the grand jury and at trial. *Id.* at 253. The potentially substantial nature of the exculpatory evidence distinguishes this case from the holding in *McDonald*.

⁹ *See also United States v. Peralta*, 763 F.Supp. 14, 19-20 (S.D.N.Y. 1991) (indictment dismissed where the cumulative effect of the government’s misleading statements of law and its use of inaccurate hearsay testimony prejudiced the defendant); *United States v. Breslin*, 916 F. Supp. 438, 442-46 (E.D. Pa. 1996) (dismissing the indictment where, among other things, the prosecutor repeatedly indicated to the grand jury that he had limited time to present his case, improperly characterized the evidence in summaries, and led the jury to believe that it was not entitled to request live witness testimony or that live testimony was unavailable).

CONCLUSION

For all of the foregoing reasons, this Court should order the government to disclose all portions of the grand jury transcripts reflecting the government's instruction or presentation by the government concerning the advice of counsel defense. In the alternative, the Court should order disclosure of the transcripts to the Court for the Court's evaluation *in camera*.

Respectfully submitted,

Dated: December 17, 2010

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